REMARKS

It is respectfully submitted that the present response presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the following remarks is requested.

I. The Rejection of Claims 6, 8, 10 and 13 under 35 U.S.C. 112 (Enablement)

Claims 6, 8, 10 and 13 stand rejected under 35 U.S.C. 112, first paragraph as allegedly lacking enablement. The Examiner states that different lipolytic enzymes have different mechanisms and different hydrolysis products and alleges that given the broad disclosure in the claims of lipolytic enzymes, one of skill in the art would not be able to make or use the invention. The Examiner further contends that the examples provided are limited with respect to the exact nature of the enzymes and therefore the scope of the claims, and that a limited showing with respect to lipolytic enzymes will encompass all enzymes regarding lipids such that there is no way to predict what other lipolytic enzymes are concerned. The Examiner further states that the quantity of experimentation is great and the specification discloses only a few specific types of lipolytic enzymes. This rejection is respectfully traversed.

It is well settled that "[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *Id.* (emphasis in original).

Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

It is also well settled that an assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974). See also *U.S. v. Telectronics*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974); *Ex parte Hitzeman*, 9 U.S.P.Q.2d 1821 (BPAI 1988).

Applicants respectfully submit that the Office's burden has not been met here.

In particular, while the Examiner's statements are directed generally to a discussion of lipolytic enzymes, nowhere does the Examiner anywhere address the actual steps of Applicants' claimed methods. On this basis alone, Applicants submit that the Examiner has not provided a properly reasoned and scientifically supported statement supporting the alleged lack of enablement of the pending claims, and therefore the enablement rejection should be withdrawn.

Moreover, Applicants' claims recite a method of selecting a lipolytic enzyme for use as a baking additive comprising incubating at least one lipolytic enzyme with N-acyl phosphatidyl ethanolamine (APE) or N-acyl lysophosphatidyl ethanolamine (ALPE), b) detecting hydrolysis of an ester bond in the APE or ALPE, c) incubating the at least one lipolytic enzyme with phosphatidyl choline (PC), d) detecting hydrolysis of an ester bond in the PC, and e) selecting a lipolytic enzyme which has a higher hydrolytic activity on ester bonds in the APE or ALPE than on ester bonds in the PC.

As set forth in the specification as filed, the screening method of the invention results in the selection of lipolytic enzymes for a higher activity on APE/ALPE than on PC. Page 3, lines 12-13. In fact, the purpose of the invention is to take advantage of the different hydrolysis rates of various lipolytic enzymes towards an ester bond in APE or ALPE as compared to the hydrolysis of an ester bond in PC in order to select a lipolytic enzyme for further testing in baking.

In this regard, the specification as filed provides exemplary lipolytic enzymes applicable to the claimed screening method. These include lipolytic enzymes known in the art such as those described in WO 00/32758, naturally occurring enzymes from microorganisms such as fungi and bacteria, as well as variants made by protein engineering. Specification, page 2, lines 2-7.

The specification as filed also provides exemplary assays for evaluating lipolytic enzymes according to the screening method of the invention. Example 3 provides screening by TLC assay, in which ten lipolytic enzymes with phospholipase activity were tested for ALPE/APE activity and PC activity. Page 6, line 14 to page 7, line 14. Example 4 provides an HPLC test for ALPE and APE, which teachings are also applicable to PC as the substrate. Page 7, lines 15-33. Example 5

provides screening by plate test using lecithin (PC) plates and APE/ALPE plates and provides the correlation that a lipolytic enzyme having higher activity on APE/ALPE than on PC can be expected to show good baking performance. Page 8, lines 1-32. Example 6 provides screening for lipolytic activity. Page 8, line 33 to page 9, line 10.

This evidence establishes that the specification teaches in detail how to conduct each and every step of the claimed methods. Based on Applicants' teaching, it would be routine for one of skill in the art to carry out the invention as claimed.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112, first paragraph (enablement). Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 6, 8, 10 and 13 under 35 U.S.C. 103

Claims 6, 8, 10 and 13 stand rejected under 35 U.S.C. 103 as allegedly being unpatentable over Clausen et al., WO 98/26057 ("R1") in view of Burdge et al., British J. Nutrition, 84, 781-787 (2000) ("R2"), Helmy et al., J. Planar Chromatography, 8, 369-373 (1995) ("R3") and Inoue et al. USPN 4,567,046 ("R4"). This rejection is respectfully traversed.

As previously stated, the claims recite a method of selecting a lipolytic enzyme for use as a baking additive comprising incubating at least one lipolytic enzyme with N-acyl phosphatidyl ethanolamine (APE) or N-acyl lysophosphatidyl ethanolamine (ALPE), b) detecting hydrolysis of an ester bond in the APE or ALPE, c) incubating the at least one lipolytic enzyme with phosphatidyl choline (PC), d) detecting hydrolysis of an ester bond in the PC, and e) selecting a lipolytic enzyme which has a higher hydrolytic activity on ester bonds in the APE or ALPE than on ester bonds in the PC.

As set forth in the specification as filed, evaluation of full-scale baking tests generally requires a major effort for isolating and producing each enzyme in sufficient quantity. Page 1, lines 9-11. In contrast to what was known in the art, the present inventors have developed a method of screening lipolytic enzymes to identify candidates for a baking additive which can improve the properties of a baked product when added to the dough. Page 1, lines 20-22. Lipolytic enzyme candidates selected according to the claimed screening methods can then be used in full-scale baking tests for further evaluation. Page 1, lines 9-11.

As correctly stated by the Examiner, R1 details the action of phospholipase A1, A2 and B, as well as the reactions of phospholipase on PC, phosphatidyl ethanolamine and lysophosphatidyl choline and assays for phospholipase. As also correctly stated, R1 teaches that the

phospholipases of the invention can be used in any application where it is desired to hydrolyze fatty acid groups, such as in the preparation of dough, bread and cakes and as bread-improving additives. R1 also teaches use of the phospholipase therein as a bread improving agent in full-scale baking tests. R1, pages 93-97, Examples 20-21.

However, nowhere does R1 teach or suggest the screening methods of Applicants' claims, and in particular, nowhere does R1 teach or suggest the selection of a lipolytic enzyme which has a higher hydrolytic activity on ester bonds in the APE or ALPE than on ester bonds in the PC. Nor do any of R2, R3 or R4 teach or suggest the claims.

R2 teaches a method for separation of phosphatidylcholine, triacylglycerol, non-esterified fatty acids and cholesterol esters from plasma by solid-phase extraction.

R3 teaches use of thin layer chromatography to assess endogenous phospholipase A capabilities in vitro.

R4 teaches bread or other cereal-based food improver containing phospholipase A and if necessary phospholipase D.

Thus, none of R1, R2, R3 or R4, either alone or in combination, teach or suggest Applicants' claimed methods.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

All required fees were charged to Novozymes North America, Inc.'s Deposit Account No. 50-1701 at the time of electronic filing. The USPTO is authorized to charge this Deposit Account should any additional fees be due.

Respectfully submitted,

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